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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299

7590

07/02/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/627,531	Applicant(s) BERRY ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-27,29-31,33-41 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-27,29-31,36-38,40 and 49-53 is/are rejected.
- 7) ☒ Claim(s) 33-35,39 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114 and preliminary amendment C, all filed 04/16/03.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 04/16/03 has been entered.
2. Applicants' arguments with respect to claims 22, 23, 27, 29 and 36 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 50 and 51 depend from generic claim 17. However, in claim 17, the solvent is limited to lauryl alcohol such that the solvent is limited only to lauryl alcohol and cannot be any thing else. However, claims 50 and 51 also limit the solvent to lauryl lactate and the solvent is

Art Unit: 1615

not permitted to be lauryl lactate since the solvent is limited in claim 17. There is insufficient antecedent basis for the solvent to be limited to lauryl lactate in claims 50 and 51.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 17-27, 29-31, 36, 37, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman (US 5,843,891).

Sherman discloses a pharmaceutical composition that comprises a drug, a solvent system and a surfactant (abstract), and Sherman's composition is directed to hydrophobic drugs that include non-polar peptides, polypeptide and protein drugs (column 1, lines 9-11 and lines 42-48, column 3, lines 5-9). The solvent system of Sherman may be a single alcohol or combination of alcohols and 1-dodecyl alcohol (lauryl alcohol) is an example of the alcohol employed in Sherman (column 3, lines 34-62, column 4, lines 13-25). Sherman in column 4, line 27 to column 5 line 30 lists surfactants that are suitable in pharmaceutical composition and polyoxyethylene-polyoxypropylene block co-polymers (POLOXAMER) and polysorbate are listed. Sherman discloses that a surfactant can also be a co-solvent (column 5, lines 35-38) when the surfactant is also an effective solvent for the drug. The composition further comprises thickening agents that are pharmaceutically acceptable polymeric materials and inorganic thickening agents (column 5, lines 54-64). Sherman's composition may also contain diluents,

Art Unit: 1615

anti-oxidants and flavoring agents (column 5, lines 65-67). Sherman further discloses that the composition can be administered as emulsion pre-concentrate, which can be further processed into emulsion and administration is via oral ingestion, parenteral or topical (column 6, lines 11-64).

Polyoxyethylene-polyoxypropylene block co-polymers satisfy the requirement for the presence of a polymer in the instant application because the disclosure of Sherman permits the surfactants to function as surfactant and carrier of solvent. The property of a composition is not separable from the composition, thus viscosity stability for extended periods or any given time are inherent properties of the broad composition where the composition comprises a surfactant, solvent and polymer and active agent. Instant claims 20 and 21 requires that the beneficial agent be at least 0.1% or 10% and a composition comprising a beneficial agent in an amount of at least 20% meets that limitation. Example 3 of Sherman discloses beneficial agent in an amount of about 22%. Therefore, the teachings of Sherman meet the limitations of the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 38, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman (US 5,843,891).

Sherman clearly teaches the composition of the instant application. Sherman also teaches parenteral and topical and oral administration of the composition to a subject in need

Art Unit: 1615

thereof. Regarding claims 38 and 40, the prior art is silent on how long the composition can be administered to a patient in need thereof, and thus the prior art teaches all modes of administration intervals. However, while Sherman in example 3 discloses 55% solvent and 22% surfactant, Sherman does not teach percent amount of the polymer. It is noted in the preceding discussion of Sherman that the surfactant can perform more than one function and a polymer is included in the composition as discussed above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition according to the teaching of Sherman. One having ordinary skill in the art would have been motivated to incorporate polyoxyethylene-polyoxypropylene block co-polymer in amounts that will serve as a carrier or co-solvent to lauryl alcohol with the expectation that the copolymer would act synergistically with the alcohol to solubilize the hydrophobic drug.

Claim Objections

10. Claim 51 is objected to because of the following informalities: Claim 51 recites "gml" without an initial definition for the term. Appropriate correction is required.

11. Claims 33-35, 39 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a method of preparing the composition where a vacuum is employed at an elevated temperature. The prior art does not teach an implant administration method.

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
June 29, 2003

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.